UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,427	06/15/2007	Daniel Mark Wallaker	61771.US	6468
	7590 08/17/201 EELY & GRAHAM, P	EXAMINER		
P O BOX 1871			GISHNOCK, NIKOLAI A	
KNOXVILLE, TN 37901			ART UNIT	PAPER NUMBER
			3715	
			MAIL DATE	DELIVERY MODE
			08/17/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	10/596,427	WALLAKER ET AL.				
Office Action Summary	Examiner	Art Unit				
	NIKOLAI A. GISHNOCK	3715				
The MAILING DATE of this communication app	ears on the cover sheet with the c	orrespondence address				
Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period v  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 13 Ju	ine 2006					
·— · · · · · · · · · · · · · · · · · ·	action is non-final.					
<del>'=</del>						
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	53 O.G. 213.				
Disposition of Claims						
4)⊠ Claim(s) <u>1-8</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-8</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	r election requirement.					
Application Papers						
9)☐ The specification is objected to by the Examine	r.					
10)⊠ The drawing(s) filed on <u>13 June 2006</u> is/are: a)⊡ accepted or b)⊠ objected to by the Examiner.						
Applicant may not request that any objection to the	drawing(s) be held in abeyance. See	e 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correct	ion is required if the drawing(s) is obj	ected to. See 37 CFR 1.121(d).				
11)☐ The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.				
Priority under 35 U.S.C. § 119						
12)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a)⊠ All b)□ Some * c)□ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list	of the certified copies not receive	d.				
Attachment(s)						
Notice of References Cited (PTO-892)     Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summary Paper No(s)/Mail Da					
3) Information Disclosure Statement(s) (PTO/SB/08)	5) 🔲 Notice of Informal P					
Paper No(s)/Mail Date <u>6/4/2007</u> . 6)						

Art Unit: 3715

#### **DETAILED ACTION**

## Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "105" in Figure 1 has been used to designate all of concentric angulation control wheels, a force feedback unit, and control knobs. The drawings are further objected to under 37 CFR 1.83(a) because they fail to show the four cables emerging from the distal end of the umbilical and passing into the connector as described in page 7, lines 17-20 of the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Figures 2, 3, & 4 further illustrate the umbilical as reference symbol "U"; however, numbers are preferred; see 37 CFR 1.84(p)(1). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Art Unit: 3715

## **Priority**

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

#### Information Disclosure Statement

3. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered. See "WO 03/658583" and "WO 04/015654" on page 2; and "GB 2383890" and "WO 03/050783" on page 6.

## Claim Objections

4. Claims 5-8 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim shall refer to other claims in the alternative only. Cumulative claiming is not permitted. See 37 CFR 1.75 & MPEP § 608.01(n). Claims 5, 7, & 8 will thus be treated as depending from claim 1.

# Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 3715

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 7. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for wherein at least one angulation cable in a real instrument corresponding to the one being simulated would extend from the user manipulatable controls to the tip of the insertion tube, such that movement of the angulation control changes the angulation of the tip, does not reasonably provide enablement for whether the feature of claim 1 is part of the simulated instrument. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Support at page 3, lines 4-30 of the instant specification suggests that this limitation actually recites a feature that is not part of the instant invention. Claims 2-8 inherit this deficiency.
- 8. Claims 1-8 are further rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 9. Claim 1 recites the limitation "the distal end of the umbilical" in lines 13-14. Claim 4 recites the above limitation in lines 2-3. There is insufficient antecedent basis for this limitation in the claim. Claims 2, 3, & 5-8 inherit this deficiency.
- 10. Claim 8 further recites "the position of the or each angulation cable" in line 2. It is unclear in the claim which angulation cable is referred to.
- 11. A claim limitation will be presumed to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3- prong analysis:
  - (A) the claim limitations must use the phrase "means for" or "step for; "
  - (B) the "means for" or "step for" must be modified by functional language; and
  - (C) the phrase "means for" or "step for" must not be modified by sufficient structure, material, or acts for achieving the specified function.

Art Unit: 3715

See MPEP 2181. With respect to the first prong of this analysis, a claim element that does not include the phrase "means for" or "step for" will not be considered to invoke 35 U.S.C. 112, sixth paragraph. If an applicant wishes to have the claim limitation treated under 35 U.S.C. 112, sixth paragraph, applicant must either: (A) amend the claim to include the phrase "means for" or "step for" in accordance with these guidelines; or (B) show that even though the phrase "means for" or "step for" is not used, the claim limitation is written as a function to be performed and does not recite sufficient structure, material, or acts which would preclude application of 35 U.S.C. 112, sixth paragraph. See *Watts v. XL Systems, Inc.*, 232 F.3d 877, 56 USPQ2d 1836 (Fed. Cir. 2000); see also *Masco Corp. v. United States*, 303 F.3d 1316, 1327, 64 USPQ2d 1182, 1189 (Fed. Cir. 2002). Thus in the instant claim 6, the limitation "wherein means are provided to retension the loop" will not be treated under under 35 U.S.C. 112, sixth paragraph; the limitation will be treated as an intended use of the instrument until otherwise demonstrated.

### Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 13. Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Alexander et al. (US), hereinafter known as Alexander.
- 14. Alexander discloses a dummy instrument for use in a simulator (a mock medical instrument, abstract), the instrument comprising a control body (endoscope, Figure 1, Item 22;

Application/Control Number: 10/596,427

Art Unit: 3715

9:28-39) with user manipulatable angulation control (thumb lever connected to communications interface, Figure 1, Items 19 & 24; 11:30-12:20), an insertion tube (navigation tube, Figure 1, Item 49; 9:18-39) and an umbilical extending from the control body (), wherein at least one angulation cable (a belt disposed about each pulley, See Figure 11a, Items 420, 424, & 426; 17:55-65) extends from the user manipulatable angulation control, down the umbilical, to the tip of the insertion tube (see Figures 1 & 3; the belt {44} is understood to connect the communications device {24} at the interface device {60}, down guide tube {34} via its inner tube {56}, to the tip of the navigation tube {49}) such that movement of the angulation control changes the angulation of the tip (12:1-20), the umbilical being releasably attached to a main unit (at capture mechanism, Figure 3, Item 38; 12:38-67; see also 9:40-10:38), a motor within the instrument at the distal end of the umbilical (active motor attached to the carrier, see Figure 3, Item 60; 26:3-10) to apply a variable force to the cable (21:26-39), and a position detector within the instrument to detect the angular position of the angulation control (encoders, all at 12:38-67) [Claim 1].

Page 6

- 15. Alexander discloses wherein the position detector measures the rotation of the control [Claim 2] and the displacement of the cable [Claim 3] (rotational and translational encoders, 10:57-11:29) [Claims 2 & 3].
- 16. Alexander discloses wherein the position detector is located at the distal end of the umbilical (Figure 3, Items 30 & 31; 12:38-67) [Claim 4].
- 17. Alexander discloses wherein the instrument is provided with two pairs of angulation cables each pair forming a loop around the control body, and around a respective motor at the distal end of the umbilical (nested instruments having multiple carriage assemblies as described, Figure 15; 22:50-23:4; it is implied that each of the multiple carriages has a belt for selectively encoding the position of each nested instrument) [Claim 5].

Art Unit: 3715

18. Alexander discloses means provided to re-tension the loop (tension spring and spring screw, Figures 17a-b, Items 816 & 832; all at 23:26-24:44) [Claim 6].

- 19. Alexander discloses wherein a connector at the distal end of the umbilical is configured to provide a two-part release, allowing release to a partially released position in which the umbilical may be rotated relative to the base unit, but in which the weight of the umbilical is still supported by the base unit, and a second fully released position in which the umbilical is completely releasable from the base unit (all at 23:5-25; the first released position is understood to be when the navigation tube is in the guide tube but not yet captured; the fully released position is as removed from the guide tube) [Claim 7].
- 20. Alexander discloses wherein the position of each angulation cable is sensed by a combination of a low resolution absolute position detector and a higher resolution incremental encoder (potentiometer and optical encoder, both at 25:63-26:3; the pot is understood to be low resolution and absolute, whereas the optical encoder is understood to be high resolution and incremental) [Claim 8].

#### **Conclusion**

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Frecker et al. (US 7,208,005 B2) and Pearson et al. (US 2003/0130771 A1) disclose using a force-feedback end connector in an endoscope.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIKOLAI A. GISHNOCK whose telephone number is (571)272-1420. The examiner can normally be reached on M-F 11:00a-7:30p EST (8:00a-4:30p PST).

Art Unit: 3715

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Xuan M. Thai can be reached on 571-272-7147. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

8/15/2010 /Nikolai A Gishnock/ Examiner, Art Unit 3715